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K 012850

Section 5: 510(k) Summary

Recording and Stimulating Electrode 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

Submitter of Premarket Notification:

Kevin J. O'Connell
Sr. Regulatory Associate
Radionics, a Division of Tyco Healthcare Group, LP
22 Terry Avenue
Burlington, MA 01803
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Performance Standards:

No applicable performance standards have been issued under section 514 of the Food, Drug & Cosmetic Act.

Device Name:

Proprietary Name:	Recording and Stimulating Electrode
Common/Usual Name:	Recording Electrode and/or Stimulating Electrode
Classification Name:	Depth Electrode

Predicate Device(s):

Radionics Microelectrode Kit, 510(k) number K991399, dated September 21, 1999.

Microrecording Systems Consultants, LLC, Microelectroencephalography Professional System 5000 for Surgical Neurophysiological Recording, 510(k) number K991077, dated June 9, 1999.

Intended Use:

To record electrical activity or evoke a response through stimulation for the purpose of brain mapping during functional neurosurgical procedures.

Device Description:

The Recording and Stimulating Electrode is a passive probe guided stereotactically to record electrical activity or evoke a response through stimulation for the purpose of brain mapping during functional neurosurgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics, a Division of Tyco Healthcare Group, LP
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K012850
Trade/Device Name: Recording and Stimulating Electrode
Regulation Number: 882.1330, 882.1310
Regulation Name: Depth electrode, Cortical electrode
Regulatory Class: II
Product Code: GZL, GYC
Dated: August 23, 2001
Received: August 24, 2001

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ODE Indications for Use Statement

510(k) Number (if known): ___K012850_____

Device Name: Recording and Stimulating Electrode

Indications for Use:

To record electrical activity or evoke a response through stimulation for the purpose of brain mapping during functional neurosurgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

Susan Walker

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012850